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DEA CHRONICLES

Drug Enforcement Administration Litigation & Compliance Issues

Judge Dissolves ISO Against West Virginia Pharmacy: Suspicion Of Diversion Not Enough to Support Suspension

By Larry P. Cote & Russell Day on November 1, 2019

In a decision issued on October 30, Judge Joseph Goodwin of the Southern District of West Virginia dissolved an Order of Immediate Suspension of Registration ("ISO") issued by DEA against Oak Hill Hometown Pharmacy, a West Virginia pharmacy. Without getting too far into the factual weeds of this case, I do think there are two or three critical takeaways related to both the adjudication of this matter and to DEA's view of Subutex vs. Suboxone.

Subutex vs. Suboxone

The prescribing of Subutex and Suboxone as part of medication assisted treatment ("MAT") for opioid addiction lies at the heart of this case. Between December 2016 and March 2019, Oak Hill Hometown Pharmacy in West Virginia ("Oak Hill") had filled about 2,000 prescriptions for Subutex. Both

Subutex and Suboxone can be employed in MAT treatment. They are different, however, and in a critical way. While both are buprenorphine products, Suboxone contains naloxone as well, which, as DEA's opposition brief states, "is intended to block the euphoric high resulting from the injection of the drug by narcotic abusers," which makes it less susceptible to abuse. Subutex contains no such blocking element. That said, Subutex is recommended for pregnant women and for anyone allergic to naloxone. This minor exception, however, cannot explain the large amount of prescriptions for Subutex by Oak Hill. This was the primary reason behind the issuance of the ISO. **The very fact that the prescriptions were for Subutex – "a widely abused controlled substance," according to the DEA brief – was the first cited "red flag" identified by DEA**. AUSA Alan McGonigal, in fact, told the Court, "You could say that the fact that it was Subutex was the primary triggering red flag."

But Is A Red Flag Alone Enough to Substantiate an ISO?

In a word, No.

Now there were other red flags posited by DEA, including the long distances traveled by patients, the high percentage of cash purchases, indications of "pattern prescribing," and the filling of prescriptions over multiple trips to the pharmacy. They were addressed somewhat cursorily, however, as the Subutex issue took front and center.

As the court indicates, to justify an ISO, DEA must show that a registrant's continued registration presents an "imminent danger to the public health or safety." This standard was further defined by Congress in 2016 to require a

showing of "a substantial likelihood of an immediate threat that death, serious bodily harm, or abuse of a controlled substance will occur in the absence of an immediate suspension of the registration."

In this case, as the Court put it, "the DEA continually points to the 2,000 prescriptions . . . as suggesting abuse and diversion." However, "more than suspicion that these prescriptions indicate abuse and diversion that would rise to the level of a danger to public health and safety" is required. Here's the key: "[T]here must be evidence that the Pharmacy was filling prescriptions that patients were abusing or diverting at the time the agency issued the ISO in August 2019." Proof of actual diversion or actual abuse is necessary, not simply suspicion based on Subutex prescription numbers. With the absence of <u>any</u> evidence of actual diversion, the ISO was dissolved.

While DEA's arguments did not ultimately prevail before the District Court, it is important to understand that, despite strong support from the **Trump Administration** and **Congress** for greater access and availability to treatment for substance use disorders, DEA maintains a rather aggressive enforcement philosophy regarding the prescribing and dispensing of single-entity buprenorphine products. This may be justified, as there <u>is</u> anecdotal evidence that these products are used for other than their intended purpose. Regardless, mere speculation or conjecture cannot be the basis for issuance of an ISO and the judge's order in this matter was appropriate.

Standard of Review

Here, I should add a comment about the standard of review used by the Court. DEA argued that the Court should use an "arbitrary and capricious"

standard. While the Court agreed that it "owes deference to the DEA's finding of fact," it argued that, as it has original jurisdiction in a case of whether or not to dissolve an ISO and that sufficient fact-finding and due process procedures are not in place in such an emergency context, *de novo* review is the appropriate standard. Should *de novo* review become the universal standard for cases involving the dissolving of ISOs, the deference to DEA is diminished – how significantly, we have yet to see.

The case is: *Oak Hill Hometown Pharmacy v. Uttam Dhillon, et al. (Civil Action No. 2:19-cv-00716)*